



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/552,485 04/18/00 SINGER C 1662/49502

026646
KENYON & KENYON
ONE BROADWAY
NEW YORK NY 10004

HM12/0823

EXAMINER

HABTELK

ART UNIT	PAPER NUMBER
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1624
DATE MAILED:

9
08/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/552,485

Applicant(s)

SINGER ET AL.

Examiner

Kahsay Habte, Ph. D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 29-45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 44 and 45 are rejected under 35 U.S.C. 102(b) as anticipated by van der Burg et al (US Pat. No. 4,062,848) or, in the alternative, under 35 U.S.C. 103(a) as obvious over van der Burg'848. Claims 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Van der Burg et al (US Pat. No. 4,062,848). Van der Burg et al. teaches the pharmaceutical formulation of mirtazapine compounds on column 1 (line 7).

Water solutions are one of the known formulations for pharmaceutical composition.

Applicants claim pharmaceutical compositions of mirtazapine adduct that is the same as Van der Burg et al. Since an adduct of mirtazapine in aqueous solution is a pharmaceutical composition and would no longer be a water adduct of mirtazapine, the same material is obtained.

Claims 44 and 45 are alternatively rejected under 35 U.S.C. 103(a) as obvious over van der Burg'848. The cited reference teaches a pharmaceutical formulations on column 1 (line 7). Applicants claim in the instant application a water adduct of mirtazapine (a mixture of water and mirtazapine). Since water is one of the known compounds used as a pharmaceutical carrier, it would have been obvious at the time of the invention is was made to the person having ordinary skill in the art to select water as a carrier to make pharmaceutical composition.

2. Claims 44 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Nickolson et al (US Pat. No. 5,977,099). Nickolson et al. recites in claim 1 (column 6, lines 9-11) "a combination comprising mirtazapine or a pharmaceutical acceptable salt thereof and at least on SSRI's or a pharmaceutically acceptable salt" that is embraced by the rejected claims. In the instant application, there has been recited in claim 44 "a pharmaceutical composition comprising a therapeutically effective amount" that is an open-end language. The phrase "comprising" is an open claim language and reads on all possible combination or composition of mirtazapine with other ingredients. Since

Art Unit: 1624

applicant's pharmaceutical composition of mirtazapine compounds are the same as Nickolson et al., a 102(e) rejection is proper. Note previous rejection.

3. Claims 29-43 are rejected under 35 U.S.C. 102(b) as being unpatentable over Kaspersen *et al.* Kaspersen *et al.* on page 1066 teaches crystallization of mirtazapine crude product from methanol/water to achieve colorless crystals. In claims 29-43, there has been recited an adduct of mirtazapine and the method of its preparation (precipitation from organic solvents such as alcohols). It appears to be the same process and therefore the products are presumed to be the same, i.e. inherently formed. See *In re Zelinski* 141 USPQ 217, *In re Best* 195 USPQ 432, and *In re Wiegand* 86 USPQ 155. Applicants can overcome the rejection over Kaspersen *et al.* by showing that their product is different from Kaspersen *et al.*, e.g. different melting point.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 36 and 42 recite "the adduct of mirtazapine and water ...containing up to about three weight percent water", but the said claims

Art Unit: 1624

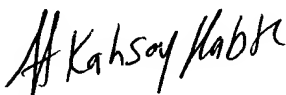
appear to be duplicates of claim 30. Whether a compound is precipitated from alcohol or any organic solvent, the final product is the same, as this is the only way to prepare.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
August 17, 2001